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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE SELENIOUS ACID LITIGATION	C.A. No. 2:24-cv-07791 (BRM) (CLW) (Consolidated)

PLAINTIFF'S ANSWER TO DEFENDANTS SUN PHARMACEUTICAL INDUSTRIES LIMITED AND SUN PHARMACEUTICAL INDUSTRIES, INC.'S ANSWER, SEPARATE DEFENSES AND COUNTERCLAIMS TO THE COMPLAINT

Plaintiff/Counterclaim Defendant American Regent, Inc. ("ARI"), by its undersigned attorneys, hereby responds to the Answer, Separate Defenses, and Counterclaims of Defendants/Counterclaimants Sun Pharmaceutical Industries Limited ("SPIL") and Sun Pharmaceutical Industries, Inc. ("SPINC") (collectively, "Sun" of "Defendants") (ECF No. 67; hereinafter, the "Counterclaims") as follows:

GENERAL DENIAL

ARI denies all allegations in Sun's Counterclaims except for those specifically admitted below. With respect to the allegations made in the Counterclaims, upon knowledge with respect to ARI's own acts, and upon information and belief as to other matters, ARI responds and alleges as follows:

NATURE OF THE ACTION

1. These Counterclaims arise under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and seek a declaratory judgment that Sun's proposed products in Abbreviated New Drug Application ("ANDA") No. 219547 do not and will not infringe any valid and enforceable claim of U.S. Patent No. 12,150,957 ("the '957 patent" or "the patent-in-suit"), and that each and every claim of the '957 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to, 35 U.S.C. §§ 102, 103 and/or 112, and/or based on other judicially created bases for invalidation.

ANSWER: Paragraph 1 states legal conclusions for which no response is required. To the extent a response is required, ARI admits that Sun purports to bring the Counterclaims under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. ARI does not contest subject matter jurisdiction in this judicial district for the purposes of this action only. ARI denies that the Counterclaims have merit or that Sun is entitled to any relief on its Counterclaims.

2. Upon information and belief, a true and complete copy of the '957 patent is attached to the Complaint (D.I. 1) as Exhibit A.

ANSWER: Admitted.

THE PARTIES

3. Defendant/Counterclaim-Plaintiff SPIL is a company incorporated under the laws of India, having a principal place of business in Mumbai, India.

ANSWER: On the basis of Sun's Answer to Paragraph 3 in the Counterclaims, admitted.

4. Defendant/Counterclaim-Plaintiff SPINC is a company incorporated under the laws of the state of Delaware, having places of business in Princeton, New Jersey and Cranbury, New Jersey.

ANSWER: On the basis of Sun's Answer to Paragraph 4 in the Counterclaims, admitted.

5. On information and belief, and based on Plaintiff/Counterclaim-Defendant's allegations, Plaintiff/Counterclaim-Defendant ARI is a corporation organized and existing under the laws of the State of New York, with a principal place of business at 5 Ramsey Road, Shirley, New York 11967.

ANSWER: Admitted.

6. ARI purports to be the lawful owner of the '957 patent.

ANSWER: Admitted.

7. ARI purports to hold the New Drug Application ("NDA") No. 209379 for Selenious Acid ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL), (2) eq. 60 mcg Selenium/mL (eq. 60 mcg Selenium/mL), and (3) eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL)) and purports to market, distribute, and sell the selenious acid products.

ANSWER: Admitted.

JURISDICTION AND VENUE

8. This Court has jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202 based on an actual controversy among the parties, arising under the patent laws of the United States, 35 U.S.C. § 1 *et seq*.

ANSWER: Paragraph 8 states legal conclusions for which no response is required. To the extent a response is required, ARI admits that Sun purports to bring the Counterclaims under the patent laws of the United States and 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202. ARI does not contest subject matter jurisdiction in this judicial district for the purposes of this action only. ARI denies that the Counterclaims have merit or that Sun is entitled to any relief on its Counterclaims.

9. This Court has personal jurisdiction over Plaintiff/Counterclaim-Defendant based on, *inter alia*, its filing of this lawsuit in this jurisdiction, and/or Plaintiff/Counterclaim-

Defendant's substantial business in and regular systematic contact with this District. Counterclaim-defendant has also availed itself of this forum in other pending actions, e.g., *American Regent, Inc. v. Gland Pharma Limited*, Civil Action No. 2-24-cv-07756; *American Regent, Inc. v. Zydus Pharmaceuticals (USA) Inc.*, Civil Action No. 2-24-cv-07812.

ANSWER: Paragraph 9 states legal conclusions for which no response is required. To the extent a response is required, ARI does not contest personal jurisdiction for purposes of this action only. ARI otherwise denies the allegations of Paragraph 9.

10. Venue is proper in this judicial district based on 28 U.S.C. §§ 1391 and 1400 and 21 U.S.C. § 355(j)(5)(C)(i)(II).

ANSWER: Paragraph 10 states legal conclusions for which no response is required. To the extent a response is required, ARI does not contest venue in this judicial district for the purposes of this action only. ARI otherwise denies the allegations of Paragraph 10.

BACKGROUND

11. According to the United States Food & Drug Administration ("FDA") publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book"), ARI holds an approved New Drug Application ("NDA") No. 209379 for selenious acid solutions.

ANSWER: Admitted.

12. Under 21 U.S.C. § 355(b)(1), an NDA holder must provide to FDA the patent numbers and expiration dates of any patent(s) that the NDA holder believes "claims the drug for which the applicant submitted the [NDA]" or which "claims a method of using such drug." FDA ministerially publishes these patents in the Orange Book.

ANSWER: Admitted.

13. Upon information and belief, and as stated in the Complaint in this matter, ARI is the owner of the '957 patent. Upon information and belief, and as stated on the face of the '957 patent, ARI is the assignee of the '957 patent.

ANSWER: Admitted.

14. Upon information and belief, ARI, itself or through its agents, caused the '957 patent to be listed in the Orange Book as a patent that claims its selenious acid products or a method of using its selenious acid products subject to NDA No. 209379.

ANSWER: Admitted.

15. The ’957 patent, on its face, is titled “Trace element compositions, methods of making and use” and has an issue date of November 26, 2024.

ANSWER: Admitted.

16. SPIL submitted ANDA No. 219547 to FDA seeking approval to engage in commercial manufacture, or sale of the products described therein (“Sun’s Proposed ANDA Product”) in the United States. SPINC is the U.S. Agent for SPIL for ANDA No. 219547.

ANSWER: ARI admits that Sun notified ARI that Sun submitted ANDA No. 219547 to market generic versions of selenious acid solutions, intravenous, 600 mcg/10 mL (eq. 60 mcg/mL). ARI otherwise denies the allegations in Paragraph 16.

17. ANDA No. 219547 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the ’957 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sun’s Proposed ANDA Product.

ANSWER: ARI admits that, through letter (the “Sun Notice Letter”), Sun notified ARI that Sun submitted ANDA No. 219547 to market generic versions of selenious acid solutions, intravenous, 600 mcg/10 mL (eq. 60 mcg/mL) prior to the expiration of the ’957 patent. ARI further admits that the Sun Notice Letter contained arguments and/or positions that the ’957 patent is invalid and/or not infringed, which are not grounded in fact or law and raise material issues to be resolved in later stages in this proceeding, including claim construction issues and patent infringement and validity issues that will be the subject of fact and expert discovery, neither of which have occurred. ARI denies that Sun’s factual and legal bases have merit. ARI otherwise denies the allegations in Paragraph 17.

18. On or around December 18, 2024, SPIL sent a notice letter providing notice of its submission of an amendment to ANDA No. 219547 to FDA (“the Notice Letter”) to ARI. The Notice Letter contains notification of SPIL’s Paragraph IV Certification to FDA that the ’957 patent is invalid, unenforceable, and/or not infringed by Sun’s Proposed ANDA Product and the factual and legal bases in support thereof. The Notice Letter also contained an offer of confidential access to ANDA No. 219547 in accordance with 21 U.S.C. § 355(j)(5)(C).

ANSWER: ARI admits that, through the Sun Notice Letter, Sun notified ARI that Sun submitted ANDA No. 219547 to market generic versions of selenious acid solutions, intravenous, 600 mcg/10 mL (eq. 60 mcg/mL) prior to the expiration of the ’957 patent. ARI admits that the Sun Notice Letter contained an offer of confidential access to ANDA No. 219547. ARI further admits that the Sun Notice Letter contained arguments and/or positions that the ’957 patent is invalid and/or not infringed, which are not grounded in fact or law and raise material issues to be resolved in later stages in this proceeding, including claim construction issues and patent infringement and validity issues that will be the subject of fact and expert discovery, neither of which have occurred. ARI denies that Sun’s factual and legal bases have merit. ARI otherwise denies the allegations in Paragraph 18.

19. On or around December 13, 2024, Plaintiff/Counterclaim-Defendant filed a lawsuit, alleging, inter alia, infringement of the ’957 patent based on SPIL’s filing of ANDA No. 219547.

ANSWER: Admitted.

20. Sun denies it infringes any valid claim of the ’957 patent.

ANSWER: On the basis of Sun’s Third Separate Defense, ARI admits that Sun denies it infringes any valid claim of the ’957 patent. ARI further denies the remaining allegations in Paragraph 20. ARI specifically denies that Sun does not infringe one or more valid claims of the ’957 patent.

21. Absent a ruling from this Court finding the ’957 patent is invalid, unenforceable, and/or not infringed by Sun or the products described in ANDA No. 219547, ARI will continue to assert the ’957 patent against Sun, hindering the ability of Sun to obtain regulatory approval and to market in the United States the products described in ANDA No. 219547, causing irreparable harm to Sun’s businesses and denying Sun patent certainty.

ANSWER: Denied.

22. ARI has requested both injunctive relief and damages against Sun. Sun has invested significant financial and other resources into the development of Sun’s Proposed ANDA Product

and in seeking FDA approval. ARI's threats against Sun will continue as long as the disputes identified with respect to the infringement and validity of the '957 patent remain.

ANSWER: ARI admits that it has requested both injunctive relief and damages against Sun. ARI lack sufficient knowledge and information to form a belief as to the truth of the remaining allegations of Paragraph 22 as pled and denies them on that basis.

23. Accordingly, there is an actual, substantial, and continuing justiciable case and controversy between ARI and Sun regarding the '957 patent, over which this Court can and should exercise jurisdiction and declare the rights of the parties.

ANSWER: Paragraph 23 states legal conclusions for which no response is required. To the extent a response is required, ARI admits there is a present, genuine, and justiciable controversy that exists between ARI and Sun regarding Sun's infringement of the '957 patent. ARI specifically denies that there is an actual, substantial, and continuing justiciable case and controversy between ARI and Sun regarding invalidity of the '957 patent.

COUNT I

(Declaration of Invalidity of the '957 Patent)

24. Sun incorporates by reference Paragraphs 1 through 23 as if fully set forth herein.

ANSWER: No response is required to the general re-allegation and incorporation by reference of the foregoing paragraphs of the counterclaims. To the extent a response is required, ARI incorporates the answers in response to the foregoing paragraphs as if fully set forth herein.

25. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Sun and ARI concerning the invalidity of the '957 patent.

ANSWER: Paragraph 25 states legal conclusions for which no response is required. To the extent a response is required, ARI admits there is a present, genuine, and justiciable controversy that exists between ARI and Sun regarding Sun's infringement of the '957 patent. ARI specifically

denies that there is an actual, substantial, and continuing justiciable case and controversy between ARI and Sun regarding invalidity of the ’957 patent.

26. One or more of the claims of the ’957 patent is invalid for failure to comply with one or more of the requirements set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

ANSWER: Denied.

27. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. §§ 2201 *et seq.*, Sun is entitled to a declaratory judgment that one or more claims of the ’957 patent is/are invalid.

ANSWER: Denied.

COUNT II

(Declaration of Non-Infringement of the ’957 Patent)

28. Sun incorporates by reference Paragraphs 1 through 27 as if fully set forth herein.

ANSWER: No response is required to the general re-allegation and incorporation by reference of the foregoing paragraphs of the counterclaims. To the extent a response is required, ARI incorporates the answers in response to the foregoing paragraphs as if fully set forth herein.

29. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Sun and ARI concerning the non-infringement of the ’957 patent.

ANSWER: Paragraph 29 states legal conclusions for which no response is required. To the extent a response is required, ARI admits there is a present, genuine, and justiciable controversy that exists between ARI and Sun regarding Sun’s infringement of the ’957 patent

30. Neither the submission of Sun’s ANDA nor any future manufacture, use, sale, offer for sale, and/or importation into the United States of Sun’s Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the ’957 patent, either literally or under the doctrine of equivalents, at least because the claims of the ’957 patent are invalid, and an invalid claim cannot be infringed.

ANSWER: Denied.

31. Additionally, for at least the reasons set forth in the Notice Letter of December 18, 2024, neither the submission of Sun's ANDA nor the manufacture, use, sale, offer for sale, and/or importation into the United States of Sun's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '957 patent, either literally or under the doctrine of equivalents, at least because Sun's Proposed ANDA Product is not covered by any valid or enforceable claims of the '957 patent.

ANSWER: Denied.

32. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201 *et seq.*, Sun is entitled to a declaratory judgment that that it has not, does not, and will not infringe, either directly or indirectly, any valid and enforceable claim of the '957 patent, either literally or under the under the doctrine of equivalents.

ANSWER: Denied.

PRAYER FOR RELIEF

ARI denies that Sun is entitled to any judgment or relief against ARI and, therefore specifically denies Paragraphs (A)–(I) of Counterclaimant Sun's Prayer for Relief.

Each averment and/or allegation contained in Sun's Counterclaims that is not specifically admitted herein is hereby denied.

ARI requests that judgment be entered in its favor, dismissing Sun's Counterclaims with prejudice, awarding ARI's attorneys' fees and costs incurred in this litigation under 35 U.S.C. § 285, and granting even further relief as the Court may deem just and proper.

Dated: January 28, 2025

By: s/ Charles H. Chevalier

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CERTIFICATE OF SERVICE

I hereby certify that on January 28, 2025, a true and correct copy of Plaintiff's Answer to Sun's Answer, Separate Defenses, and Counterclaims to the Complaint was served by ECF on all counsel of record and electronic mail on all counsel of record for Sun.

Date: January 28, 2025

s/ Charles H. Chevalier

Charles H. Chevalier